AMENDED CLAIMS

[received by the International Bureau on 01 September 2003 (01.09.03); original claims 1-11 unchanged, new claims 12-15 added, original claims 12-27 renumbered as claims 16-31 (5 pages)]

1. The use of particulate derivatised carbohydrates in dry powder pharmaceutical compositions for inhalation therapy in order to improve stability performance.

2. The use of particulate derivatised carbohydrates in dry powder pharmaceutical compositions for inhalation therapy in order to eliminate or reduce the detrimental effect on fine particle dose caused on storage of said compositions.

3. A dry powder pharmaceutical composition for inhalation therapy comprising a pharmaceutically active agent, an excipient and a derivatised carbohydrate in particulate form.

4. A dry powder pharmaceutical composition according to claim 3 in which the derivatised carbohydrate is a mono or di-saccharide in which at least one hydroxyl group of the carbohydrate group is substituted with a hydrophobic moiety via either ester or ethers linkages.

5. A dry powder pharmaceutical composition according to claims 3 or 4 in which the derivatised carbohydrate is a carbohydrate selected from fructose, glucose, mannitol, maltose, mannitol, trehalose, cellobiose, lactose and sucrose in which at least one hydroxyl group of said carbohydrate is substituted by a straight or branched hydrocarbon chain comprising up to 20 carbon atoms.

6. A dry powder pharmaceutical composition according to any one of claims 3 - 5 in which the derivatised carbohydrate is selected from the group consisting of cellobiose octaacetate, sucrose octaacetate, lactose octaacetate, glucose pentaacetate, mannitol hexaacetate and trehalose octaacetate.

7. A dry powder pharmaceutical composition according to claim 3 in which the derivatised carbohydrate is α-D cellobiose octaacetate.

8. A dry powder pharmaceutical composition according to any one of claims 3 - 7 in which the derivatised carbohydrate is present at a concentration of less than 10% of the total composition.

9. A dry powder pharmaceutical composition according to any one of claims 3 - 8 in which the derivatised carbohydrate has an aerodynamic size in the range 1 - 20μm.

10. A dry powder pharmaceutical composition according to any one of claims 3 - 9 in which one component of the excipient that has a particle size of less than 15μm (the fine excipient component) and another component of the excipient that has a particle size of greater than 20μm but lower than 150μm (the coarse excipient component).

11. A dry powder pharmaceutical composition according to claim 10 in which the fine and coarse excipient components are both lactose.

12. A dry powder pharmaceutical composition according to any of claims 3 - 11 in which the pharmaceutically active agent is 6α, 9α-Difluoro-17α-[(2-furanylcarbonyl)oxy]-11β-hydroxy-16α-methyl-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-fluoromethyl ester.

13. A dry powder pharmaceutical composition according to any of claims 3 - 11 in which the pharmaceutically active agent is 6α, 9α-Difluoro-11β-hydroxy-16α-methyl-17α-[(4-methyl-1.3-thiazole-5-carbonyl)oxy]-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-fluoromethyl.

14. A dry powder pharmaceutical composition according to any of claims 3 - 11 in which the pharmaceutically active agent is 3-(4-[[6-({(2R)-2-hydroxy-2-[4-hydroxy-3-(hydroxymethyl)-phenyl]ethyl}amino)hexyl]oxy)butyl)benzene sulfonamide.

15. A dry powder pharmaceutical composition according to any of claims 3 - 11 in which the pharmaceutically active agent is 3-(3-[[7-({(2R)-2-hydroxy-2-[4-

hydroxy-3-hydroxymethyl)phenyl]ethyl]-amino)heptyl]oxy}propyl) benzenesulfonamide.

16. A method of treatment or prophylaxis of respiratory disorders which comprise administering to a patient in need thereof a dry powder pharmaceutical composition according to any one of claims 3 - 15.

17. Use of a dry powder pharmaceutical composition according to any one of claims 3 - 15 in the manufacture of a medicament for the treatment of respiratory disorders.

18. An inhalation device containing therein a dry powder pharmaceutical composition according to any one of claims 3 - 15.

19. An inhalation device according to claim 18 in which the dry powder pharmaceutical composition is released from a pre-metered unit medicament pack.

20. A medicament pack for use in an inhalation device which comprises an elongate strip formed from a base sheet having a plurality of recesses spaced along its length and a lid sheet hermetically but peelably sealed thereto to define a plurality of containers, each container having therein an inhalable composition according to any one of claims 3 - 15.

21. A medicament pack according to claim 20 wherein the strip is sufficiently flexible to be wound into a roll.

22. A medicament pack according to claim 20 wherein the lid sheet and base sheet have leading end portions which are not sealed to one another.

23. A medicament pack according to claim 22 wherein at least one of the said leading end portions is constructed to be attached to a winding means.

24. A medicament pack according to claim 20 wherein the hermetic seal between the base and lid sheets extends over their whole width.

25. A medicament pack according to claim 20 wherein the lid sheet may be peeled from the base sheet in a longitudinal direction from a first end of the said base sheet.

26. An inhalation device for use with a medicament pack according to any one of claims 20 - 25 which comprises an inhalable composition according to any one of claims 3 - 15, said device comprising:

(i) an opening station for receiving a container of a medicament pack being used with said inhalation device;

(ii) means positioned to engage peelable sheets of a container which has been received in said opening station for peeling apart the peelable sheets, to open such a container;

(iii) an outlet, positioned to be in communication with an opened container, through which a user can inhale medicament in powder form from such an opened container; and

(iv) indexing means for indexing in communication with said outlet containers of a medicament pack in use with said inhalation device.

27. A medicament pack comprising a circular carrier disc which has a plurality of pre-filled, hermetically sealed containers formed integrally therewith and arranged in a circle, each container containing an inhalable composition according to any one of claims 3 - 15, each container being puncturable to form a hole on each side thereof to allow in use, air to flow through the container to entrain the powder contained therein.

28. An inhalation device by which inhalable compositions according to any one of claims 3 - 15 may be administered to a patient which comprises a housing, a tray mounted and capable of moving within said housing (via a plunger) adapted to receive a circular carrier disc medicament pack according to claim 27, an air inlet (through which air can enter said device) and an air outlet (through which a patient may inhale and receive said composition.

29. A medicament pack comprising a piercable capsule which contains an inhalable composition according to any one of claims 3 - 15.

30. An inhalation device by which inhalable compositions according to any one of claims 3 - 15 may be administered to a patient which comprises a body shell which has a nozzle at a forward end and which is open at the rear end, a sleeve fitted on the outside of the body shell and rotatable with respect to it, a means for retaining a piercable capsule according to claim 29 extending through the rear wall of the sleeve into the body shell, means for piercing said capsule when sleeve is rotated and a guard to ensure that the composition and not the pierced capsule, passes through the nozzle.

31. An inhalation device by which inhalable compositions according to any one of claims 3 to 15 may be administered to a patient which comprises a nozzle, an air conduit connected to said nozzle for allowing a passage of air to be inhaled, a dosing unit comprising a storage chamber for the composition (which may also comprise a dosage indicating means) and a displaceable element for dispensing said composition from the storage chamber into the air conduit, a manoeuvering unit for displacing said element in relation to the storage chamber and optional deflector devices to provide accelerated airflow.